UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549
FORM 10-Q

(Mark One)
☒ QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
For the quarterly period ended June 30, 2020

Or

☐ TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
For the transition period from __________ to __________

Commission file number: 001-36333

Bio-Path Holdings, Inc.

(Exact name of registrant as specified in its charter)

Delaware	87-0652870
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)
4710 Bellaire Boulevard, Suite 210, Bellaire, Texas	77401
(Address of principal executive offices)	(Zip Code)

(832) 742-1357
(Registrant's telephone number, including area code)

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol	Name of each exchange on which registered
Common Stock, par value $0.001 per share	BPTH	The Nasdaq Capital Market

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes ☒ No ☐

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes ☒ No ☐

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer ☐	Accelerated filer ☐
Non-accelerated filer ☒	Smaller reporting company ☒
	Emerging growth company ☐

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes ☐ No ☒

At August 7, 2020, the Company had 3,691,857 outstanding shares of common stock, par value $0.001 per share.

Unless the context requires otherwise, references in this Quarterly Report on Form 10-Q to "we," "our," "us," "the Company" and "Bio-Path" refer to Bio-Path Holdings, Inc. and its wholly-owned subsidiary. Bio-Path Holdings, Inc.'s wholly-owned subsidiary, Bio-Path, Inc., is sometimes referred to herein as "Bio-Path Subsidiary."

CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Quarterly Report on Form 10-Q contains "forward-looking statements" within the meaning of Section 27A of the Securities Act of 1933, as amended (the "Securities Act"), and Section 21E of the Securities Exchange Act of 1934, as amended (the "Exchange Act"). Forward-looking statements can be identified by words such as "anticipate," "expect," "intend," "plan," "believe," "seek," "estimate," "project," "goal," "strategy," "future," "likely," "may," "should," "will" and variations of these words and similar references to future periods, although not all forward-looking statements contain these identifying words. Forward-looking statements are neither historical facts nor assurances of future performance. Instead, they are based on our current beliefs, expectations and assumptions regarding the future of our business, future plans and strategies, projections, anticipated events and trends, the economy and other future conditions. Because forward-looking statements relate to the future, they are subject to inherent risks, uncertainties and changes in circumstances, including those discussed in "Item 1A. Risk Factors" to Part I of our Annual Report on Form 10-K as of the fiscal year ended December 31, 2019, and in other reports or documents we file with the U.S. Securities and Exchange Commission ("SEC"). As a result, our actual results and financial condition may differ materially from those expressed or forecasted in the forward-looking statements, and you should not rely on such forward-looking statements. We can give no assurances that any of the events anticipated by the forward-looking statements will occur or, if any of them do, what impact they will have on our results of operations and financial condition. Important factors that could cause our actual results and financial condition to differ materially from those indicated in the forward-looking statements include, among others, the following:

- the impact, risks and uncertainties related to COVID-19 and actions taken by governmental authorities or others in connection therewith;
- our lack of significant revenue to date, our history of recurring operating losses and our expectation of future operating losses;
- our need for substantial additional capital and our need to delay, reduce or eliminate our drug development and commercialization efforts if we are unable to raise additional capital;
- the highly-competitive nature of the pharmaceutical and biotechnology industry and our ability to compete effectively;
- the success of our plans to use collaboration arrangements to leverage our capabilities;
- our ability to retain and attract key personnel;
- the risk of misconduct of our employees, agents, consultants and commercial partners;
- disruptions to our operations due to expansions of our operations;
- the costs we would incur if we acquire or license technologies, resources or drug candidates;
- risks associated with product liability claims;
- our reliance on information technology systems and the liability or interruption associated with cyber-attacks or other breaches of our systems;
- our ability to use net operating loss carryforwards;
- provisions in our charter documents and state law that may prevent a change in control;
- work slowdown or stoppage at government agencies could negatively impact our business;
- our need to complete extensive clinical trials and the risk that we may not be able to demonstrate the safety and efficacy of our drug candidates;
- risks that that our clinical trials may be delayed or terminated;
- our ability to obtain domestic and foreign regulatory approval for our drug candidates;
- changes in existing laws and regulations affecting the healthcare industry;
- our reliance on third parties to conduct clinical trials for our drug candidates;
- our ability to maintain orphan drug exclusivity for our drug candidates;
- our reliance on third parties for manufacturing our clinical drug supplies;
- risks associated with the manufacture of our drug candidates;
- our ability to establish sales and marketing capabilities relating to our drug candidates;

- market acceptance of our drug candidates;
- third-party payor reimbursement practices;
- our ability to adequately protect the intellectual property of our drug candidates;
- infringement on the intellectual property rights of third parties;
- costs and time relating to litigation regarding intellectual property rights;
- our ability to adequately prevent disclosure by our employees or others of trade secrets and other proprietary information;
- our need to raise additional capital;
- the volatility of the trading price of our common stock;
- our common stock being thinly traded;
- our ability to issue shares of common or preferred stock without approval from our stockholders;
- our ability to pay cash dividends;
- costs and expenses associated with being a public company; and
- our ability to maintain compliance with the listing standards of the Nasdaq Capital Market.

Please also refer to "Item 1A. Risk Factors" to Part I of our Annual Report on Form 10-K as of the fiscal year ended December 31, 2019, "Item 1A. Risk Factors" to Part II of this Quarterly Report on Form 10-Q and other reports or documents we file with the SEC for a discussion of risks and factors that could cause our actual results and financial condition to differ materially from those expressed or forecasted in this Quarterly Report on Form 10-Q.

Any forward-looking statement made by us in this Quarterly Report on Form 10-Q is based only on information currently available to us and speaks only as of the date on which it is made. We undertake no obligation to publicly update any forward-looking statement, whether as a result of new information, future developments or otherwise. However, you should carefully review the risk factors set forth in other reports or documents we file from time to time with the SEC.

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PART I – FINANCIAL INFORMATION
ITEM 1. FINANCIAL STATEMENTS

BIO-PATH HOLDINGS, INC.
CONDENSED CONSOLIDATED BALANCE SHEETS
(In thousands, except par value)
(Unaudited)

	As of June 30, 2020	As of December 31, 2019
Assets		
Current assets		
Cash	$ 14,411	$ 20,426
Prepaid drug product for testing	1,079	776
Other current assets	1,434	788
Total current assets	16,924	21,990
Fixed assets		
Furniture, fixtures & equipment	1,029	1,029
Less accumulated depreciation	(762)	(726)
	267	303
Right of use operating assets	329	367
Total Assets	$ 17,520	$ 22,660
Liabilities & Shareholders' Equity		
Current liabilities		
Accounts payable	$ 726	$ 486
Accrued expenses	410	673
Current portion of lease liabilities	89	85
Total current liabilities	1,225	1,244
Noncurrent lease liabilities	284	330
Total Liabilities	1,509	1,574
Shareholders' equity		
Preferred stock, $.001 par value;		
10,000 shares authorized; no shares issued and outstanding	-	-
Common stock, $.001 par value; 200,000 shares authorized;	4	4
3,692 and 3,692 shares issued and outstanding, respectively		
Additional paid in capital	77,710	77,421
Accumulated deficit	(61,703)	(56,339)
Total shareholders' equity	16,011	21,086
Total Liabilities & Shareholders' Equity	$ 17,520	$ 22,660

SEE ACCOMPANYING NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

BIO-PATH HOLDINGS, INC.
CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS
(In thousands, except per share amounts)
(Unaudited)

	Three Months Ended June 30		Six Months Ended June 30,	
	2020	**2019**	**2020**	**2019**
Operating expenses				
Research and development	$ 1,030	$ 1,523	$ 3,038	$ 1,921
General and administrative	1,013	966	2,349	2,088
Total operating expenses	2,043	2,489	5,387	4,009
Net operating loss	$ (2,043)	$ (2,489)	$ (5,387)	$ (4,009)
Other income				
Interest income	3	33	23	41
Total other income	3	33	23	41
Net loss	$ (2,040)	$ (2,456)	$ (5,364)	$ (3,968)
Net loss per share, basic and diluted	$ (0.55)	$ (0.87)	$ (1.45)	$ (1.75)
Basic and diluted weighted average number of common shares outstanding	3,692	2,828	3,692	2,267

SEE ACCOMPANYING NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

BIO-PATH HOLDINGS, INC.
CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS
(In thousands)
(Unaudited)

	Six Months Ended June 30, 2020	Six Months Ended June 30, 2019
Cash flow from operating activities		
Net loss	$ (5,364)	$ (3,968)
Adjustments to reconcile net loss to net cash used in operating activities		
Stock-based compensation	289	338
Amortization of right of use assets	38	56
Depreciation	36	99
(Increase) decrease in operating assets		
Prepaid drug product for testing	(303)	(322)
Other current assets	(646)	(42)
Increase (decrease) in operating liabilities		
Accounts payable and accrued expenses	(23)	(328)
Lease liabilities	(42)	(56)
Net cash used in operating activities	(6,015)	(4,223)
Cash flow from financing activities		
Net proceeds from sale of common stock	-	19,411
Net proceeds from exercise of warrants	-	914
Net cash provided by financing activities	-	20,325
Net (decrease) increase in cash	**(6,015)**	**16,102**
Cash, beginning of period	20,426	1,004
Cash, end of period	$ 14,411	$ 17,106

SEE ACCOMPANYING NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

BIO-PATH HOLDINGS, INC.

CONDENSED CONSOLIDATED STATEMENTS OF SHAREHOLDERS' EQUITY
(In thousands)
(Unaudited)

Description	Common Stock Shares	Common Stock Amount	Additional Paid in Capital	Accumulated Deficit	Total
Balance at March 31, 2019	**2,814**	**$ 3**	**$ 69,392**	**$ (49,252)**	**$ 20,143**
Exercise of warrants, net of fees	17	-	45	-	45
Stock-based compensation	-	-	181	-	181
Net loss	-	-	-	(2,456)	(2,456)
Balance at June 30, 2019	**2,831**	**$ 3**	**$ 69,618**	**$ (51,708)**	**$ 17,913**
Balance at March 31, 2020	**3,692**	**$ 4**	**$ 77,591**	**$ (59,663)**	**$ 17,932**
Stock-based compensation	-	-	119	-	119
Net loss	-	-	-	(2,040)	(2,040)
Balance at June 30, 2020	**3,692**	**$ 4**	**$ 77,710**	**$ (61,703)**	**$ 16,011**

Description	Common Stock Shares	Common Stock Amount	Additional Paid in Capital	Accumulated Deficit	Total
Balance at December 31, 2018	**680**	**$ 1**	**$ 48,957**	**$ (47,740)**	**$ 1,218**
Issuance of common stock, net of fees	1,794	2	19,409	-	19,411
Exercise of warrants, net of fees	357	-	914	-	914
Stock-based compensation	-	-	338	-	338
Net loss	-	-	-	(3,968)	(3,968)
Balance at June 30, 2019	**2,831**	**$ 3**	**$ 69,618**	**$ (51,708)**	**$ 17,913**
Balance at December 31, 2019	**3,692**	**$ 4**	**$ 77,421**	**$ (56,339)**	**$ 21,086**
Stock-based compensation	-	-	289	-	289
Net loss	-	-	-	(5,364)	(5,364)
Balance at June 30, 2020	**3,692**	**$ 4**	**$ 77,710**	**$ (61,703)**	**$ 16,011**

SEE ACCOMPANYING NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

BIO-PATH HOLDINGS, INC.

Notes to the Unaudited Condensed Consolidated Financial Statements
for the Period Ended June 30, 2020

Unless the context requires otherwise, references in these Notes to the Condensed Consolidated Financial Statements to “we,” “our,” “us,” “the Company” and “Bio-Path” refer to Bio-Path Holdings, Inc. and its subsidiary. Bio-Path Holdings, Inc.’s wholly-owned subsidiary, Bio-Path, Inc., is sometimes referred to herein as “Bio-Path Subsidiary.”

The accompanying unaudited condensed interim financial statements have been prepared in conformity with the authoritative U.S. generally accepted accounting principles (GAAP) for interim financial information and in accordance with the instructions to Form 10-Q pursuant to the rules and regulations of the Securities and Exchange Commission (“SEC”) and, therefore, do not include all information and footnotes required by GAAP for complete consolidated financial statements. In the opinion of management, all adjustments considered necessary for a fair presentation of the results of operations and financial position have been included and all such adjustments are of a normal recurring nature. The unaudited quarterly financial statements should be read in conjunction with the audited financial statements and notes thereto included in the Annual Report on Form 10-K of the Company as of and for the fiscal year ended December 31, 2019. The results of operations for the period ended June 30, 2020, are not necessarily indicative of the results for a full-year period.

1. Organization and Business

The Company is a clinical and preclinical stage oncology focused RNAi nanoparticle drug development company utilizing a novel technology that achieves systemic delivery for target specific protein inhibition for any gene product that is over-expressed in disease. The Company’s drug delivery and antisense technology, called DNAbilize®, is a platform that uses P-ethoxy, which is a deoxyribonucleic acid (DNA) backbone modification that is intended to protect the DNA from destruction by the body’s enzymes when circulating *in vivo,* incorporated inside of a lipid bilayer having neutral charge. The Company believes this combination allows for high efficiency loading of antisense DNA into non-toxic, cell-membrane-like structures for delivery of the antisense drug substance into cells. *In vivo,* the DNAbilize® delivered antisense drug substances are systemically distributed throughout the body to allow for reduction or elimination of target proteins in blood diseases and solid tumors. DNAbilize® is a registered trademark of the Company. Using DNAbilize® as a platform for drug development and manufacturing, the Company currently has four antisense drug candidates in development to treat at least five different cancer disease indications.

Bio-Path Subsidiary was founded in May 2007 as a Utah corporation. In February 2008, Bio-Path Subsidiary completed a reverse merger with the Company, which at the time was traded over the counter and had no current operations. The prior name of the Company was changed to Bio-Path Holdings, Inc. and the directors and officers of Bio-Path Subsidiary became the directors and officers of Bio-Path Holdings, Inc. The Company’s operations to date have been limited to organizing and staffing the Company, acquiring, developing and securing its technology and undertaking product development for a limited number of product candidates.

As the Company has not begun its planned principal operations of commercializing a product candidate, the Company’s activities are subject to significant risks and uncertainties, including the potential requirement to secure additional funding, the outcome of the Company’s clinical trials, and failing to operationalize the Company’s current drug candidates before another company develops similar products.

2. Significant Accounting Policies

Net Loss Per Share - Basic net loss per common share is computed by dividing the net loss for the period by the weighted average number of shares of common stock outstanding during the period. Although there were warrants and stock options outstanding as of June 30, 2020 and 2019, no potential common shares are included in the computation of any diluted per share amount, as they would be antidilutive. Consequently, diluted net loss per share as presented in the condensed consolidated financial statements is equal to basic net loss per share for the three and six months ended June 30, 2020 and 2019. The calculation of diluted earnings per share did not include 267,321 shares and 858,698 shares issuable pursuant to the exercise of outstanding common stock options and warrants, respectively, as of June 30, 2020 as the effect would be antidilutive. The calculation of diluted earnings per share for 2019 did not include 71,133 shares and 256,574 shares issuable pursuant to the exercise of outstanding common stock options and warrants, respectively, as of June 30, 2019 as the effect would be antidilutive.

Fair Value - The fair values of cash and cash equivalents, accounts payable and accrued liabilities approximate their carrying values because of the short-term maturities of these instruments.

3. Prepaid Drug Product for Testing

Advance payments, including nonrefundable amounts, for goods or services that will be used or rendered for future clinical development activities are deferred and capitalized. Such amounts will be recognized as an expense as the related goods are delivered or the related services are performed. The Company recognized certain expenses and incurred installment costs for its contract drug manufacturing and raw material suppliers with prepayments totaling \$0.8 million as of December 31, 2019 pursuant to drug supply contracts for the manufacture and delivery of prexigebersen for testing in two Phase 2 clinical trials and Bcl-2 for testing in a Phase 1 clinical trial. The Company recognized certain expenses and incurred additional installment costs during the first six months of 2020, with advanced payments remaining to be expensed totaling \$1.1 million as of June 30, 2020.

4. Other Current Assets

As of June 30, 2020, other current assets included prepaid expenses of \$1.4 million, comprised primarily of prepayments made for the Company's clinical trials for prexigebersen in AML, BP1002 in lymphoma and prexigebersen-A in solid tumors of \$0.6 million, prepaid insurance of \$0.5 million, prepayments for BP1003 manufacturing activities of \$0.2 million and other prepaid expenses of \$0.1 million. As of December 31, 2019, other current assets included prepaid expenses of \$0.8 million, comprised primarily of prepayments made for the Company's clinical trials for prexigebersen in AML and CML of \$0.6 million and prepaid insurance of \$0.2 million.

5. Accounts Payable

As of June 30, 2020, current liabilities included accounts payable of \$0.7 million, comprised primarily of amounts owed for external research expenses related to manufacturing costs of \$0.3 million, amounts owed to the Company's clinical research organization for its clinical trials for prexigebersen in AML and prexigebersen-A in solid tumors of \$0.2 million, legal and patent fees of \$0.1 million and preclinical expenses of \$0.1 million. As of December 31, 2019, current liabilities included accounts payable of \$0.5 million, comprised primarily of amounts owed for external research expenses related to manufacturing costs of \$0.3 million and legal and patent fees of \$0.2 million.

6. Accrued Expense

As of June 30, 2020, current liabilities included accrued expenses of \$0.4 million, comprised primarily of accrued employee vacation and bonus expenses of \$0.2 million, legal and patent fees of \$0.1 million and other accrued expenses of \$0.1 million. As of December 31, 2019, current liabilities included accrued expenses of \$0.7 million, comprised primarily of accrued employee vacation and bonus expenses of \$0.4 million, clinical and preclinical expenses of \$0.2 million and other accrued expenses of \$0.1 million.

7. Stockholders' Equity

Issuances of Common Stock - On January 14, 2019, the Company entered into an underwriting agreement with H.C. Wainwright & Co., LLC relating to an underwritten public offering of 429,616 shares of its common stock for gross proceeds of approximately \$1.1 million (the "2019 Underwritten Offering"). The offering price to the public in the 2019 Underwritten Offering was \$2.60 per share, and H.C. Wainwright & Co., LLC agreed to purchase the shares in the 2019 Underwritten Offering from the Company pursuant to the underwriting agreement at a price of \$2.418 per share. Additionally, the Company issued warrants to purchase up to 25,777 shares of its common stock in a private placement to H.C. Wainwright & Co., LLC as compensation for its services as underwriter in connection with the 2019 Underwritten Offering. The 2019 Underwritten Offering closed on January 17, 2019. The net proceeds to the Company from the 2019 Underwritten Offering, after deducting the underwriting discounts and commissions and expenses and the Company's offering expenses, and excluding the proceeds, if any, from the exercise of the underwriter warrants, were approximately \$0.9 million.

On January 18, 2019, the Company entered into a securities purchase agreement with certain investors pursuant to which the Company agreed to sell, in a registered direct offering, an aggregate of 648,233 shares of its common stock for gross proceeds of approximately \$1.7 million (the "January 2019 Registered Direct Offering"). In a concurrent private placement, the Company also agreed pursuant to the securities purchase agreement to issue to such investors Series A warrants to purchase up to 324,117 shares of its common stock (the "January 2019 Private Placement"). Additionally, the Company issued warrants to purchase up to 38,894 shares of its common stock in a private placement to H.C. Wainwright& Co., LLC as compensation for its services as a placement agent in connection with the 2019 Registered Direct Offering and the 2019 Private Placement. The 2019 Registered Direct Offering and the 2019 Private Placement closed on January 23, 2019. The net proceeds to the Company from the offerings, after deducting the placement agent's fees and expenses, offering expenses, and excluding the proceeds, if any, from the exercise of the warrants issued in the offerings, were approximately \$1.5 million.

On March 12, 2019, the Company entered into a securities purchase agreement with certain investors pursuant to which the Company agreed to sell, in a registered direct offering, an aggregate of 712,910 shares of its common stock for gross proceeds of approximately $18.5 million (the "March 2019 Registered Direct Offering"). Additionally, the Company issued warrants to purchase up to 42,775 shares of its common stock in a private placement to H.C. Wainwright & Co., LLC as compensation for its services as a placement agent in connection with the March 2019 Registered Direct Offering. The March 2019 Registered Direct Offering closed on March 14, 2019. The net proceeds to the Company from the offerings, after deducting the placement agent's fees and expenses, offering expenses, and excluding the proceeds, if any, from the exercise of the warrants issued in the offerings, were approximately $17.0 million.

On November 21, 2019, the Company entered into a securities purchase agreement with certain investors pursuant to which the Company agreed to sell, in a registered direct offering, an aggregate of 808,080 shares of its common stock and warrants to purchase up to 606,060 shares of its common stock for gross proceeds of approximately $8.0 million under the 2019 Shelf Registration Statement (the "November 2019 Registered Direct Offering"). Additionally, the Company issued warrants to purchase up to 48,485 shares of its common stock to H.C. Wainwright & Co., LLC as compensation for its services as a placement agent in connection with the November 2019 Registered Direct Offering, which warrants and the common stock issuable upon exercise of such warrants were registered under the 2019 Shelf Registration Statement. The November 2019 Registered Direct Offering closed on November 25, 2019. The net proceeds to the Company from the offerings, after deducting the placement agent's fees and expenses, offering expenses, and excluding the proceeds, if any, from the exercise of the warrants issued in the offerings, were approximately $7.3 million.

During the fiscal year ended December 31, 2019, the Company issued an aggregate of 409,875 shares of its common stock pursuant to the exercise of warrants at a weighted average exercise price of approximately $2.67 per share. The net proceeds to the Company from the exercise of the warrants were approximately $1.1 million.

8. Stock-Based Compensation Plan

The 2017 Plan – On December 21, 2017, the Company's stockholders approved the Bio-Path Holdings, Inc. 2017 Stock Incentive Plan (as amended, the "2017 Plan"), which replaced the First Amended 2007 Stock Incentive Plan, as amended (the "2007 Plan"). The 2007 Plan expired by its terms in January 2018, and no awards were made under the 2007 Plan from the approval of the 2017 Plan on December 21, 2017 until the expiration of the 2007 Plan. The 2017 Plan provides for the grant of Incentive Stock Options, Non-Qualified Stock Options, Restricted Shares, Restricted Share Units, Stock Appreciation Rights, Performance-Based Awards and other stock-based awards, or any combination of the foregoing to the Company's employees, non-employee directors and consultants. On December 19, 2019, the Company's stockholders approved an amendment to the 2017 Plan to increase the number of shares reserved for grant and issuance pursuant to the 2017 Plan by 600,000 shares to 660,000 shares. Under the 2017 Plan, the exercise price of awards is determined by the Board of Directors or the compensation committee of the Board of Directors, and for options intended to qualify as qualified Incentive Stock Options, may not be less than the fair market value as determined by the closing stock price at the date of the grant. Each option and award under the 2017 Plan shall vest and expire as determined by the Board of Directors or the compensation committee. Options expire no later than ten years from the date of grant. All grants provide for accelerated vesting if there is a change of control, as defined in the 2017 Plan.

Stock-based compensation expense for the three months ended June 30, 2020 and 2019 was $0.1 million and $0.2 million, respectively. Of these amounts, stock-based compensation expense for personnel involved in the Company's general and administrative activities for the three months ended June 30, 2020 and 2019 was $0.1 million and $0.2 million, respectively. Stock-based compensation expense for personnel involved in the Company's research and development activities for the three months ended June 30, 2020 and 2019 was $24,000 and $26,000, respectively.

Stock-based compensation expense for each of the six months ended June 30, 2020 and 2019 was $0.3 million. Of these amounts, stock-based compensation expense for personnel involved in the Company's general and administrative activities for the six months ended June 30, 2020 and 2019 was $0.2 million and $0.3 million, respectively. Stock-based compensation expense for personnel involved in the Company's research and development activities for the six months ended June 30, 2020 and 2019 was $45,000 and $0.1 million, respectively.

The Company utilized the Black-Scholes valuation model for estimating the fair value of the stock options granted, with the following weighted-average assumptions for options granted in the six months ended June 30, 2020 and 2019, respectively:

	2020	2019
Risk-free interest rate	0.50%	2.23%
Expected volatility	122%	126%
Expected term in years	6.0	6.0
Dividend yield	-%	-%

The following summary represents option activity under the Company's stock-based compensation plans for the six months ended June 30, 2020:

	Options (in thousands)	Weighted-Average Exercise Price
Outstanding at December 31, 2019	68	$ 68.56
Granted	204	5.01
Forfeited	(4)	7.19
Expired	(1)	28.54
Outstanding at June 30, 2020	267	20.98
Exercisable at June 30, 2020	45	$ 88.48

As of June 30, 2020, the aggregate intrinsic value of outstanding stock options was $27,000. The aggregate intrinsic value represents the total pretax intrinsic value (the difference between the Company's closing stock price on June 30, 2020 and the exercise price, multiplied by the number of in-the-money options) that would have been received by the option holders had all option holders exercised their options on June 30, 2020. This amount changes based on the fair value of the Company's stock.

As of June 30, 2020, unamortized stock-based compensation expense for all outstanding options was $1.1 million, which is expected to be recognized over a remaining weighted average vesting period of 2.8 years.

9. Commitments and Contingencies

Drug Supplier Project Plan – Total commitments for the Company's drug supplier project plan are $1.1 million as of June 30, 2020, comprised of $0.7 million to the manufacturer of prexigebersen and BP1002 drug products, $0.3 million for manufacture of the Company's Grb2, Bcl-2, and STAT3 drug substances, and $0.1 million for manufacturing development. The Company expects to incur $0.7 million of these commitments over the next 12 months.

10. Subsequent Events

As previously disclosed, on June 24, 2015, the Company entered into a Controlled Equity Offering℠ Sales Agreement (the "Sales Agreement") with Cantor Fitzgerald & Co. ("Cantor Fitzgerald"), pursuant to which the Company could offer and sell, at the Company's option, shares of its common stock for aggregate gross sales proceeds of up to $25.0 million, from time to time, through an "at the market" equity offering program under which Cantor Fitzgerald acted as agent. On July 2, 2020, the Company delivered written notice to Cantor Fitzgerald that it had elected, pursuant to Section 12(b) of the Sales Agreement, to terminate the Sales Agreement effective as of July 12, 2020, ten (10) days after delivery of the notice. The Company did not incur any material early termination penalties in connection with the termination of the Sales Agreement. The Company did not sell any shares of common stock pursuant to the Sales Agreement.

On July 13, 2020, the Company entered into an At-The-Market Offering Agreement (the "Offering Agreement") with H. C. Wainwright & Co., LLC ("Wainwright"), as sales agent and/or principal, pursuant to which the Company may offer and sell, from time to time, through or to Wainwright, shares of the Company's common stock. Sales of shares of common stock under the Offering Agreement will be made pursuant to the Company's shelf registration statement on Form S-3 filed with the SEC, which was declared effective by the SEC on June 5, 2019 (File No. 333-231537), and a related prospectus supplement filed with the SEC on July 14, 2020, for an aggregate offering price of up to $7.0 million, provided that the Company may be limited in the amount of securities that it can sell under the Offering Agreement pursuant to Instruction I.B.6 to Form S-3 for so long as the Company's public float remains less than $75.0 million. Under the Offering Agreement, Wainwright may sell shares by any method deemed to be an "at the market" offering as defined in Rule 415 under the Securities Act. The Company will pay Wainwright a commission of 3% of the aggregate gross proceeds from each sale of shares under the Offering Agreement and has agreed to provide Wainwright with customary indemnification and contribution rights. The Company has also agreed to reimburse Wainwright for certain specified expenses. To date, the Company has not offered or sold any shares of common stock under the Offering Agreement.

ITEM 2. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

When you read this Item of this Quarterly Report on Form 10-Q, it is important that you also read the unaudited financial statements and related notes included elsewhere in this Quarterly Report on Form 10-Q and our audited financial statements and notes thereto included in our Annual Report on Form 10-K as of the fiscal year ended December 31, 2019. This Quarterly Report on Form 10-Q contains forward-looking statements that involve risks and uncertainties, such as statements of our plans, objectives, expectations, and intentions. We use words such as "anticipate," "estimate," "plan," "project," "continuing," "ongoing," "expect," "believe," "intend," "may," "will," "should," "could," and similar expressions to identify forward-looking statements. Our actual results could differ materially from those anticipated in these forward-looking statements due to the impact, risks and uncertainties related to COVID-19 and actions taken by governmental authorities or others in connection therewith. To date, COVID-19's impact on our operations has been limited to the inability to travel to clinical trial sites and clinical trial sites not allowing nonessential personnel on site for the purpose of monitoring activity. We anticipate COVID-19 may have an effect on patient recruiting in the near term as social distancing mandates are in effect. We believe these operational issues can be managed through remote monitoring capabilities currently being developed. Our actual results could also differ materially from those anticipated in these forward-looking statements for many other reasons, including the matters discussed in "Item 1A. Risk Factors" to Part I of our Annual Report on Form 10-K as of the fiscal year ended December 31, 2019, the matters discussed in "Item 1A. Risk Factors" to Part II of this Quarterly Report on Form 10-Q, and other risks and uncertainties discussed in filings made with the SEC. See "Cautionary Note Regarding Forward-Looking Statements" in this Quarterly Report on Form 10-Q for additional discussion regarding risks associated with forward-looking statements.

Overview

We are a clinical and preclinical stage oncology focused RNAi nanoparticle drug development company utilizing a novel technology that achieves systemic delivery for target specific protein inhibition for any gene product that is over-expressed in disease. Our drug delivery and antisense technology, called DNAbilize®, is a platform that uses P-ethoxy, which is a deoxyribonucleic acid (DNA) backbone modification that is intended to protect the DNA from destruction by the body's enzymes when circulating in vivo, incorporated inside of a lipid bilayer having neutral charge. We believe this combination allows for high efficiency loading of antisense DNA into non-toxic, cell-membrane-like structures for delivery of the antisense drug substance into cells. *In vivo*, the DNAbilize® delivered antisense drug substances are systemically distributed throughout the body to allow for reduction or elimination of target proteins in blood diseases and solid tumors. Through testing in numerous animal studies and treatment in over 70 patients, the Company's DNAbilize® drug candidates have demonstrated an excellent safety profile. DNAbilize® is a registered trademark of the Company.

Using DNAbilize® as a platform for drug development and manufacturing, we currently have four drug candidates in development to treat at least five different cancer disease indications. Our lead drug candidate, prexigebersen (pronounced prex" i je ber' sen), initially started the efficacy portion of a Phase 2 clinical trial for untreated or de novo acute myeloid leukemia ("AML") patients in combination with low-dose cytarabine ("LDAC"). Subsequently, a second cohort of untreated AML patients was added to the clinical trial for treatment with prexigebersen in combination with decitabine. On March 6, 2019, we announced intended Stage 2 amendments to this Phase 2 clinical trial to (i) add high risk myelodysplastic syndrome ("MDS") patients to the untreated AML cohort being treated with prexigebersen in combination with decitabine, (ii) close the prexigebersen in combination with LDAC treatment cohort, (iii) add a cohort of relapsed/refractory AML and high risk MDS patients for treatment with prexigebersen and decitabine and (iv) following successful completion of a safety segment treating AML and MDS patients with prexigebersen in combination with decitabine, add venetoclax to the treatment combination treating all patient cohorts with prexigebersen in combination with decitabine and venetoclax. On November 26, 2019, we announced successful completion of safety testing of the treatment combination of prexigebersen and decitabine in AML and MDS patients in Stage 2 of this Phase 2 clinical trial.

In addition, preclinical efficacy studies for the triple combination treatment of prexigebersen, decitabine and venetoclax in AML have been successfully completed. In the preclinical efficacy studies, four AML cancer cell lines were treated with three different combinations of decitabine, venetoclax and prexigebersen. Decrease in AML cell viability was the primary measure of efficacy. The triple combination of decitabine, venetoclax and prexigebersen showed significant improvement in efficacy in three of the four AML cell lines. Based on these results, the Company believes that adding prexigebersen to the treatment combination of decitabine and venetoclax could lead to improved efficacy in AML patients. Based on the successful completion of these studies, we submitted the amendment for Stage 2 of this Phase 2 clinical trial to add the triple combination treatment comprised of prexigebersen, decitabine and venetoclax to the U.S. Food and Drug Administration ("FDA"). We added a third cohort to the amendment submitted, treating relapsed/refractory patients who are venetoclax resistant or intolerant with the two-drug combination of prexigebersen and decitabine. The FDA requested that the treatment of MDS patients with the triple combination of prexigebersen, decitabine and venetoclax be conducted in a separate clinical trial. As a result, the amendment was modified and resubmitted to the FDA for approval.

The required amount of time has passed since submission to the FDA allowing clearance to proceed with testing under the amendment to Stage 2 of this Phase 2 clinical trial. The result of these changes is that the approved amended protocol for the Stage 2 of this Phase 2 trial in AML is comprised of two cohorts, one having untreated AML patients and the second having relapsed/refractory AML patients, both treated with the triple combination of decitabine, venetoclax and prexigebersen, and a third cohort of relapsed/refractory AML patients, who are venetoclax resistant or intolerant, treated with the two-drug combination of decitabine and prexigebersen. The full trial design plans have approximately 98 evaluable patients for the first cohort having untreated AML patients with a preliminary review performed after 19 evaluable patients and a formal interim analysis after 38 evaluable patients. The full trial design plans have approximately 54 evaluable patients for each of the second cohort, having relapsed/refractory AML patients, and the third cohort, having AML patients who are venetoclax resistant or intolerant, in each case with a review performed after 19 evaluable patients. The study is anticipated to be conducted at ten clinical sites in the U.S., and Gail J. Roboz, MD will be the national coordinating Principal Investigator for the Phase 2 trial. Dr. Roboz is professor of medicine and director of the Clinical and Translational Leukemia Program at the Weill Medical College of Cornell University and the New York-Presbyterian Hospital in New York City. On August 13, 2020, we announced the enrollment and dosing of the first patient in this approved amended Stage 2 of the Phase 2 clinical study.

In addition, a modified product named prexigebersen-A, Bio-Path's fourth drug candidate, has shown to enhance chemotherapy efficacy in preclinical solid tumor models. Prexigebersen-A incorporates the same drug substance as prexigebersen but has a slightly modified formulation designed to enhance nanoparticle properties. In late 2019, we filed an Investigational New Drug ("IND") application to initiate a Phase 1 clinical trial of prexigebersen-A in patients with solid tumors, including ovarian and uterine, pancreatic and breast cancer. Ovarian cancer is one of the most common type of gynecologic malignancies, with approximately 50% of all cases occurring in women older than 63 years. This trial is expected to commence after the IND has been cleared by the FDA, which we currently anticipate being in 2020.

Our second drug candidate, Liposomal Bcl-2 ("BP1002"), targets the protein Bcl-2, which is responsible for driving cell survival in up to 60% of all cancers. On November 21, 2019, we announced that the FDA cleared an IND application for BP1002. An initial Phase 1 clinical trial will evaluate the ability of BP1002 to treat refractory/relapsed lymphoma and chronic lymphocytic leukemia patients. The Phase 1 clinical trial is expected to be conducted at several leading cancer centers, including The University of Texas MD Anderson Cancer Center ("MD Anderson"), the Georgia Cancer Center and the Sarah Cannon Research Institute and is now open for enrollment.

Our third drug candidate, Liposomal STAT3 ("BP1003"), targets the STAT3 protein and is currently in IND enabling studies as a potential treatment of pancreatic cancer, non-small cell lung cancer (NSCLC) and AML. Preclinical models have shown BP1003 to inhibit cell viability and STAT3 protein expression in NSCLC and AML cell lines. Further, BP1003 successfully penetrated pancreatic tumors and significantly enhanced the efficacy of gemcitabine, a treatment for patients with advanced pancreatic cancer, in a pancreatic cancer patient derived tumor model. Our lead indication for BP1003 is pancreatic cancer due to the severity of this disease and the lack of effective, life-extending treatments. For example, pancreatic adenocarcinoma is projected to be the second most lethal cancer behind lung cancer by 2030. Typical survival for a metastatic or advanced patient is about six to 15 months from diagnosis. We expect to complete several IND enabling studies of BP1003 in 2020. If those studies are successful, our goal is to file an IND in late 2020 for the first-in-humans Phase 1 study of BP1003 in patients with refractory/metastatic solid tumors, including pancreatic, NSCLC and colorectal cancers.

Our DNAbilize® technology-based products are available for out-licensing or partnering. We intend to apply our drug delivery technology template to new disease-causing protein targets to develop new nanoparticle antisense RNAi drug candidates. We have a new product identification template in place to define a process of scientific, preclinical, commercial and intellectual property evaluation of potential new drug candidates for inclusion into our drug product development pipeline. As we expand, we will look at indications where a systemic delivery is needed and antisense RNAi nanoparticles can be used to slow, reverse or cure a disease, either alone or in combination with another drug. On September 25, 2019, we announced that the United States Patent and Trademark Office ("USPTO") issued a patent for claims related to DNAbilize®, including its use in the treatment of cancers, autoimmune diseases and infectious diseases. This is the second patent issued to the Company.

We have certain intellectual property as the basis for our current drug products in clinical development, prexigebersen, prexigebersen-A, BP1002 and BP1003. We are developing RNAi antisense nanoparticle drug candidates based on our own patented technology to treat cancer and autoimmune disorders where targeting a single protein may be advantageous and result in reduced patient adverse effects as compared to small molecule inhibitors with off-target and non-specific effects. We have composition of matter and method of use intellectual property for the design and manufacture of antisense RNAi nanoparticle drug products.

On July 13, 2020, we entered into an At-The-Market Offering Agreement (the "Offering Agreement") with H. C. Wainwright & Co., LLC ("Wainwright"), as sales agent and/or principal, pursuant to which we may offer and sell, from time to time, through or to Wainwright, shares of our common stock. Sales of shares of common stock under the Offering Agreement will be made pursuant to our shelf registration statement on Form S-3 filed with the SEC, which was declared effective by the SEC on June 5, 2019 (File No. 333-231537), and a related prospectus supplement filed with the SEC on July 14, 2020, for an aggregate offering price of up to $7.0 million, provided that we may be limited in the amount of securities that we can sell under the Offering Agreement pursuant to Instruction I.B.6 to Form S-3 for so long as our public float remains less than $75.0 million. Under the Offering Agreement, Wainwright may sell shares by any method deemed to be an "at the market" offering as defined in Rule 415 under the Securities Act. We will pay Wainwright a commission of 3% of the aggregate gross proceeds from each sale of shares under the Offering Agreement and have agreed to provide Wainwright with customary indemnification and contribution rights. We have also agreed to reimburse Wainwright for certain specified expenses.

As of June 30, 2020, we had an accumulated deficit of $61.7 million. Our net loss was $2.0 million and $2.5 million for the three months ended June 30, 2020 and 2019, respectively. Our net loss was $5.4 million and $4.0 million for the six months ended June 30, 2020 and 2019, respectively. We expect to continue to incur significant operating losses, and we anticipate that our losses may increase substantially as we expand our drug development programs and commercialization efforts. To achieve profitability, we must enter into license or development agreements with third parties, or successfully develop and obtain regulatory approval for one or more of our drug candidates and effectively commercialize any drug candidates we develop. In addition, if we obtain regulatory approval of one or more of our drug candidates, we expect to incur significant commercialization expenses related to product sales, marketing, manufacturing and distribution. Even if we succeed in developing and commercializing one or more of our drug candidates, we may not be able to generate sufficient revenue and we may never be able to achieve or sustain profitability. We expect to finance our foreseeable cash requirements through cash on hand, cash from operations, debt financings and public or private equity offerings. We may seek to access the public or private equity markets whenever conditions are favorable; however, there can be no assurance that we will be able to raise additional capital when needed or on terms that are favorable to us, if at all. Additionally, we may seek collaborations and license arrangements for our drug candidates. We currently have no lines of credit or other arranged access to debt financing.

Company History and Available Information

The Company was incorporated in May 2000 as a Utah corporation. In February 2008, Bio-Path Subsidiary completed a reverse merger with the Company, which at the time was traded over the counter and had no current operations. The prior name of the Company was changed to Bio-Path Holdings, Inc. and the directors and officers of Bio-Path Subsidiary became the directors and officers of Bio-Path Holdings, Inc. On March 10, 2014, our common stock ceased trading on the OTCQX and commenced trading on the Nasdaq Capital Market under the ticker symbol "BPTH." Effective December 31, 2014, we changed our state of incorporation from Utah to Delaware through a statutory conversion pursuant to the Utah Revised Business Corporation Act and the Delaware General Corporation Law. Our principal executive offices are located at 4710 Bellaire Boulevard, Suite 210, Bellaire, Texas 77401, and our telephone number is (832) 742-1357.

On February 8, 2018, we effected a reverse stock split of our outstanding shares of common stock at a ratio of 1-for-10, and our common stock began trading on the split-adjusted basis on the Nasdaq Capital Market at the commencement of trading on February 9, 2018. In addition, on January 17, 2019, we effected a reverse stock split of our outstanding shares of common stock at a ratio of 1-for-20, and our common stock began trading on the split-adjusted basis on the Nasdaq Capital Market at the commencement of trading on January 18, 2019. All common stock share and per share amounts in this Quarterly Report on Form 10-Q have been adjusted to give effect to both the 1-for-10 reverse stock split and the 1-for-20 reverse stock split, retrospectively.

Recent Accounting Pronouncements

There are no recent accounting pronouncements that have a material impact on our condensed consolidated financial statements.

Financial Operations Overview

Revenue

We have not generated significant revenues to date. Our ability to generate revenues from our drug candidates, which we do not expect will occur for many years, if ever, will depend heavily on the successful development and eventual commercialization of our drug candidates.

In the future, we may generate revenue from a combination of product sales, third-party grants, service agreements, strategic alliances and licensing arrangements. We expect that any revenue we generate will fluctuate due to the timing and amount of services performed, milestones achieved, license fees earned and payments received upon the eventual sales of our drug candidates, in the event any are successfully commercialized. If we fail to complete the development of any of our drug candidates or obtain regulatory approval for them, our ability to generate future revenue will be adversely affected.

Research and development expenses

Research and development expenses consist of costs associated with our research activities, including the development of our drug candidates. Our research and development expenses consist of:

- expenses related to research and development personnel, including salaries and benefits, travel and stock-based compensation;
- external research and development expenses incurred under arrangements with third parties, such as contract research organizations, clinical investigative sites, laboratories, manufacturing organizations and consultants; and
- costs of materials used during research and development activities.

Costs and expenses that can be clearly identified as research and development are charged to expense as incurred in accordance with generally accepted accounting policies ("GAAP"). Advance payments, including nonrefundable amounts, for goods or services that will be used or rendered for future research and development activities are deferred and capitalized. Such amounts will be recognized as an expense as the related goods are delivered or the related services are performed. If the goods will not be delivered, or services will not be rendered, then the capitalized advance payment is charged to expense.

We expect research and development expenses associated with the completion of the associated clinical trials to be substantial and to increase over time. The successful development of our drug candidates is highly uncertain. At this time, we cannot reasonably estimate or know the nature, timing and estimated costs of the efforts that will be necessary to complete development of our drug candidates or the period, if any, in which material net cash inflows from our drug candidates may commence. This is due to the numerous risks and uncertainties associated with developing drugs, including the uncertainty of:

- the rate of progress, results and costs of completion of ongoing clinical trials of our drug candidates;
- the size, scope, rate of progress, results and costs of completion of any potential future clinical trials and preclinical trials of our drug candidates that we may initiate;
- competing technological and market developments;
- the performance of third-party manufacturers and suppliers;
- the ability of our drug candidates, if they receive regulatory approval, to achieve market success;
- disputes or other developments relating to proprietary rights, including patents, litigation matters and our ability to obtain patent protection for our drug candidates; and
- the impact, risks and uncertainties related to COVID-19 and actions taken by governmental authorities or others in connection therewith.

A change in the outcome of any of these variables with respect to the development of a drug candidate could mean a significant change in the costs and timing associated with the development of that drug candidate. For example, if the FDA or other regulatory authority were to require us to conduct clinical trials beyond those which we currently anticipate will be required for the completion of clinical development of a drug candidate or if we experience significant delays in enrollment in any clinical trials, we could be required to expend significant additional financial resources and time on the completion of clinical development.

General and administrative expenses

Our general and administrative expenses consist primarily of salaries and benefits for management and administrative personnel, professional fees for legal, accounting and other services, travel costs and facility-related costs such as rent, utilities and other general office expenses.

Results of Operations

Comparisons of the Three Months Ended June 30, 2020 to the Three Months Ended June 30, 2019

Research and Development Expense. Our research and development expense for the three months ended June 30, 2020 was $1.0 million, a decrease of $0.5 million compared to the three months ended June 30, 2019. The decrease in research and development expense was primarily due to timing of activities related to our Phase 2 clinical trial of prexigebersen in AML. The following table sets forth our research and development expenses (in thousands):

	Three Months Ended June 30,	
	2020	**2019**
Research and development expense	$ 1,006	$ 1,497
Non-cash stock-based compensation expense	24	26
Total research and development expense	$ 1,030	$ 1,523

General and Administrative Expense. Our general and administrative expense was $1.0 million for each of the three months ended June 30, 2020 and 2019. The following table sets forth our general and administrative expenses (in thousands):

	Three Months Ended June 30,	
	2020	**2019**
General and administrative expense	$ 918	$ 811
Non-cash stock-based compensation expense	95	155
Total general and administrative expense	$ 1,013	$ 966

Net Operating Loss. Our net loss from operations for the three months ended June 30, 2020 was $2.0 million, a decrease of $0.4 million compared to the three months ended June 30, 2019.

Net Loss. Our net loss for the three months ended June 30, 2020 was $2.0 million, a decrease of $0.4 million compared to the three months ended June 30, 2019.

Net Loss per Share. Net loss per share, both basic and diluted, was $0.55 per share for the three months ended June 30, 2020, compared to $0.87 per share for the three months ended June 30, 2019. Net loss per share is calculated using the weighted average number of shares of common stock outstanding during the applicable periods and excludes stock options and warrants because they are antidilutive.

Comparisons of the Six Months Ended June 30, 2020 to the Six Months Ended June 30, 2019

Research and Development Expense. Our research and development expense for the six months ended June 30, 2020 was $3.0 million, an increase of $1.1 million compared to the six months ended June 30, 2019. The increase in research and development expense was primarily due to the manufacture of drug material in preparation for our Phase 1 clinical trial of prexigebersen-A in solid tumors and increased preclinical study expenses. The following table sets forth our research and development expenses (in thousands):

	Six Months Ended June 30,	
	2020	**2019**
Research and development expense	$ 2,993	$ 1,870
Non-cash stock-based compensation expense	45	51
Total research and development expense	$ 3,038	$ 1,921

General and Administrative Expense. Our general and administrative expense for the six months ended June 30, 2020 was $2.3 million, an increase of $0.3 million compared to the six months ended June 30, 2019. The increase in general and administrative expense was primarily due to increased franchise tax expense. The following table sets forth our general and administrative expenses (in thousands):

	Six Months Ended June 30,	
	2020	**2019**
General and administrative expense	$ 2,105	$ 1,801
Non-cash stock-based compensation expense	244	287
Total general and administrative expense	$ 2,349	$ 2,088

Net Operating Loss. Our net loss from operations for the six months ended June 30, 2020 was $5.4 million, an increase of $1.4 million compared to the six months ended June 30, 2019.

Net Loss. Our net loss for the six months ended June 30, 2020 was $5.4 million, an increase of $1.4 million compared to the six months ended June 30, 2019.

Net Loss per Share. Net loss per share, both basic and diluted, was $1.45 per share for the six months ended June 30, 2020, compared to $1.75 per share for the six months ended June 30, 2019. Net loss per share is calculated using the weighted average number of shares of common stock outstanding during the applicable periods and excludes stock options and warrants because they are antidilutive.

Liquidity and Capital Resources

Overview

We have not generated significant revenues to date. Since our inception, we have funded our operations primarily through public and private offerings of our capital stock and other securities. We expect to finance our foreseeable cash requirements through cash on hand, cash from operations, debt financings and public or private equity offerings. We may seek to access the public or private equity markets whenever conditions are favorable; however, there can be no assurance that we will be able to raise additional capital when needed or on terms that are favorable to us, if at all. Additionally, we may seek collaborations and license arrangements for our drug candidates. We currently have no lines of credit or other arranged access to debt financing.

We had a cash balance of $14.4 million as of June 30, 2020, a decrease of $6.0 million compared to December 31, 2019. We believe that our available cash at June 30, 2020 will be sufficient to meet obligations and fund our liquidity and capital expenditure requirements for at least the next 12 months.

Cash Flows

Operating Activities. Net cash used in operating activities for the six months ended June 30, 2020 was $6.0 million. Excluding non-cash stock-based compensation expense of $0.3 million, such net cash used in operating activities consisted primarily of the net loss for the period of $5.4 million and an increase in current assets of $0.9 million. Net cash used in operating activities for the six months ended June 30, 2019 was $4.2 million. Excluding non-cash stock-based compensation expense of $0.3 million and depreciation and amortization expenses of $0.2 million, such net cash used in operating activities consisted primarily of the net loss for the period of $4.0 million, an increase in current assets of $0.4 million and a decrease in current liabilities of $0.4 million.

Financing Activities. There were no financing activities for the six months ended June 30, 2020. Net cash provided by financing activities for the six months ended June 30, 2019 was $20.3 million. Net cash provided by financing activities consisted primarily of net proceeds of $19.4 million from the 2019 Underwritten Offering, the January 2019 Registered Direct Offering and January 2019 Private Placement and the March 2019 Registered Direct Offering, each as described below, as well as net proceeds of $0.9 million from the exercise of warrants to purchase shares of our common stock.

2019 Shelf Registration Statement

On May 16, 2019, we filed a shelf registration statement on Form S-3 with the SEC, which was declared effective by the SEC on June 5, 2019 (File No. 333-231537) (the "2019 Shelf Registration Statement"), at which time the offering of unsold securities under a previous shelf registration statement on Form S-3 filed with the SEC, which was declared effective by the SEC on January 9, 2017 (File No. 333-215205) (the "2017 Shelf Registration Statement"), was deemed terminated pursuant to Rule 415(a)(6) under the Securities Act. The 2019 Shelf Registration Statement was filed to register the offering, issuance and sale of (i) up to $125.0 million of our common stock, preferred stock, warrants to purchase common stock or preferred stock or any combination thereof, either individually or in units, and (ii) up to 5,149 shares of our common stock pursuant to the exercise of warrants that were issued in connection with a registered direct offering in 2016. Because our public float is less than $75 million, our ability to offer and sell any securities under the 2019 Shelf Registration Statement is currently limited pursuant to Instruction I.B.6 to Form S-3. For so long as the Company's public float is less than $75 million, the aggregate market value of securities sold by the Company under the 2019 Shelf Registration Statement pursuant to Instruction I.B.6 to Form S-3 during any 12 consecutive months may not exceed one-third of the Company's public float. The foregoing does not constitute an offer to sell or the solicitation of an offer to buy securities, and shall not constitute an offer, solicitation or sale in any jurisdiction in which such offer, solicitation or sale would be unlawful prior to registration or qualification under the securities laws of that jurisdiction.

2019 Underwritten Offering

On January 14, 2019, we entered into an underwriting agreement with Wainwright relating to an underwritten public offering of 429,616 shares of our common stock for gross proceeds of approximately $1.1 million under the 2017 Shelf Registration Statement (the "2019 Underwritten Offering"). The offering price to the public in the 2019 Underwritten Offering was $2.60 per share, and Wainwright agreed to purchase the shares in the 2019 Underwritten Offering from the Company pursuant to the underwriting agreement at a price of $2.418 per share. Additionally, we issued warrants to purchase up to 25,777 shares of our common stock in a private placement to Wainwright as compensation for its services as underwriter in connection with the 2019 Underwritten Offering. The 2019 Underwritten Offering closed on January 17, 2019. The net proceeds to the Company from the 2019 Underwritten Offering, after deducting the underwriting discounts and commissions and expenses and the Company's estimated offering expenses, and excluding the proceeds, if any, from the exercise of the underwriter warrants, were approximately $0.9 million.

January 2019 Registered Direct Offering and January 2019 Private Placement

On January 18, 2019, we entered into a securities purchase agreement with certain investors pursuant to which we agreed to sell, in a registered direct offering, an aggregate of 648,233 shares of our common stock for gross proceeds of approximately $1.7 million under the 2017 Shelf Registration Statement (the "January 2019 Registered Direct Offering"). In a concurrent private placement, we also agreed pursuant to the securities purchase agreement to issue to such investors Series A warrants to purchase up to 324,117 shares of our common stock (the "January 2019 Private Placement"). Additionally, we issued warrants to purchase up to 38,894 shares of our common stock in a private placement to Wainwright as compensation for its services as a placement agent in connection with the 2019 Registered Direct Offering and the January 2019 Private Placement. The January 2019 Registered Direct Offering and the January 2019 Private Placement closed on January 23, 2019. The net proceeds to the Company from the offerings, after deducting the placement agent's fees and expenses, our offering expenses, and excluding the proceeds, if any, from the exercise of the warrants issued in the offerings, were approximately $1.5 million.

March 2019 Registered Direct Offering

On March 12, 2019, we entered into a securities purchase agreement with certain investors pursuant to which we agreed to sell, in a registered direct offering, an aggregate of 712,910 shares of our common stock for gross proceeds of approximately $18.5 million under the 2017 Shelf Registration Statement (the "March 2019 Registered Direct Offering"). Additionally, we issued warrants to purchase up to 42,775 shares of our common stock in a private placement to Wainwright as compensation for its services as a placement agent in connection with the March 2019 Registered Direct Offering. The March 2019 Registered Direct Offering closed on March 14, 2019. The net proceeds to us from the offerings, after deducting the placement agent's fees and expenses, our offering expenses, and excluding the proceeds, if any, from the exercise of the warrants issued in the offerings, were approximately $17.0 million.

November 2019 Registered Direct Offering

On November 21, 2019, we entered into a securities purchase agreement with certain investors pursuant to which we agreed to sell, in a registered direct offering, an aggregate of 808,080 shares of our common stock and warrants to purchase up to 606,060 shares of our common stock for gross proceeds of approximately $8.0 million under the 2019 Shelf Registration Statement (the "November 2019 Registered Direct Offering"). Additionally, we issued warrants to purchase up to 48,485 shares of our common stock to Wainwright as compensation for its services as a placement agent in connection with the November 2019 Registered Direct Offering, which warrants and the common stock issuable upon exercise of such warrants were registered under the 2019 Shelf Registration Statement. The November 2019 Registered Direct Offering closed on November 25, 2019. The net proceeds to us from the offerings, after deducting the placement agent's fees and expenses, our offering expenses, and excluding the proceeds, if any, from the exercise of the warrants issued in the offerings, were approximately $7.3 million.

At-The-Market Offering Agreement

On July 13, 2020, we entered into the Offering Agreement with Wainwright, as sales agent and/or principal, pursuant to which we may offer and sell, from time to time, through or to Wainwright, shares of our common stock. Sales of shares of common stock under the Offering Agreement will be made pursuant to the 2019 Shelf Registration Statement and a related prospectus supplement filed with the SEC on July 14, 2020, for an aggregate offering price of up to $7.0 million, provided that we may be limited in the amount of securities that we can sell under the Offering Agreement pursuant to Instruction I.B.6 to Form S-3 for so long as our public float remains less than $75.0 million. Under the Offering Agreement, Wainwright may sell shares by any method deemed to be an "at the market" offering as defined in Rule 415 under the Securities Act. We will pay Wainwright a commission of 3% of the aggregate gross proceeds from each sale of shares under the Offering Agreement and have agreed to provide Wainwright with customary indemnification and contribution rights. We have also agreed to reimburse Wainwright for certain specified expenses. To date, we have not offered or sold any shares of common stock under the Offering Agreement.

Future Capital Requirements

We expect to continue to incur significant operating expenses in connection with our ongoing activities, including conducting clinical trials, manufacturing and seeking regulatory approval of our drug candidates prexigebersen, prexigebersen-A, BP1002 and BP1003. Accordingly, we will continue to require substantial additional capital to fund our projected operating requirements. Such additional capital may not be available when needed or on terms favorable to us. In addition, we may seek additional capital due to favorable market conditions or strategic considerations, even if we believe we have sufficient funds for our current and future operating plan. There can be no assurance that we will be able to continue to raise additional capital through the sale of our securities in the future. Our future capital requirements may change and will depend on numerous factors, which are discussed in detail in "Item 1A. Risk Factors" to Part I of our Annual Report on Form 10-K as of the fiscal year ended December 31, 2019. For more information, see Note 1 to the Unaudited Condensed Consolidated Financial Statements included herein.

Off-Balance Sheet Arrangements

As of June 30, 2020, we did not have any material off-balance sheet arrangements.

Critical Accounting Policies

The preparation of financial statements in conformity with GAAP in the United States has required the management of the Company to make assumptions, estimates and judgments that affect the amounts reported in the financial statements, including the notes thereto, and related disclosures of commitments and contingencies, if any. We consider our critical accounting policies to be those that require the more significant judgments and estimates in the preparation of financial statements. There have been no significant changes to our critical accounting policies from those disclosed in Note 2 to our Consolidated Financial Statements included in our Annual Report on Form 10-K as of the year ended December 31, 2019.

ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

Not applicable.

ITEM 4. CONTROLS AND PROCEDURES

Evaluation of Disclosure Controls and Procedures

It is management's responsibility to establish and maintain adequate disclosure controls and procedures, as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act. Disclosure controls and procedures are controls and other procedures of a company that are designed to ensure that information required to be disclosed by the company in the reports that it files or submits under the Exchange Act is recorded, processed, summarized and reported, within the time periods specified in the SEC's rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is accumulated and communicated to management, including the company's principal executive and principal financial officers, as appropriate, to allow timely decisions regarding required disclosure.

Our management, including our Chief Executive Officer (who is also our Chief Financial Officer), has reviewed and evaluated the effectiveness of our disclosure controls and procedures, as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act, as of the end of the period covered by this Quarterly Report on Form 10-Q. Following this review and evaluation, our management determined that as of the end of the period covered by this Quarterly Report on Form 10-Q, our disclosure controls and procedures were effective to ensure that information required to be disclosed by us in reports that we file or submit under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in SEC rules and forms, and is accumulated and communicated to management, including our Chief Executive Officer and our Chief Financial Officer, as appropriate, to allow timely decisions regarding required disclosure.

Changes in Internal Control over Financial Reporting

There were no changes in our internal control over financial reporting that occurred during the period covered by this Quarterly Report on Form 10-Q that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

PART II – OTHER INFORMATION

ITEM 1. LEGAL PROCEEDINGS

None.

ITEM 1A. RISK FACTORS

There were no material changes from the risk factors previously disclosed under "Item 1A. Risk Factors" to Part I of our Annual Report on Form 10-K as of the fiscal year ended December 31, 2019, other than the additional disclosure of the risk factor listed below.

The COVID-19 pandemic could adversely impact our business, including our clinical trials.

In December 2019, a novel strain of coronavirus, COVID-19, was reported to have surfaced in Wuhan, China. Since then, COVID-19 has evolved into a global pandemic, spreading to many countries, including the United States. Depending upon the severity of the COVID-19 outbreak, we may experience disruptions that could severely impact our business.

For instance, our clinical trials may be affected by the pandemic. Site initiation, participant recruitment and enrollment, participant dosing, distribution of clinical trial materials, study monitoring and data analysis may be paused or delayed due to changes in hospital or university policies, federal, state or local regulations, prioritization of hospital resources toward pandemic efforts, or other reasons related to the pandemic. If COVID-19 continues to spread, some participants and clinical investigators may not be able to comply with clinical trial protocols. For example, quarantines or other travel limitations (whether voluntary or required) may impede participant movement, affect sponsor access to study sites, or interrupt healthcare services, and we may be unable to conduct our clinical trials. Additionally, infections and deaths related to the pandemic may disrupt the United States' healthcare and healthcare regulatory systems. Such disruptions could divert healthcare resources away from, or materially delay FDA review and/or approval of, our clinical trials. It is unknown how long these disruptions could continue, were they to occur. Any elongation or de-prioritization of our clinical trials or delay in regulatory review resulting from such disruptions could materially affect the development and study of our product candidates.

To date, COVID-19's impact on our operations has been limited to the inability to travel to clinical trial sites and clinical trial sites not allowing nonessential personnel on site for the purpose of monitoring activity. We anticipate COVID-19 may have an effect on patient recruiting in the near term as social distancing mandates are in effect. We believe these operational issues can be managed through remote monitoring capabilities currently being developed.

The global outbreak of COVID-19 continues to rapidly evolve. The extent to which COVID-19 may impact our business, including our clinical trials, will depend on future developments, which are highly uncertain and cannot be predicted with confidence, such as the duration of the outbreak, travel restrictions and social distancing in the United States and other countries, business closures or business disruptions and the effectiveness of actions taken in the United States and other countries to contain and treat the disease. We will continue to monitor the situation closely.

ITEM 2. UNREGISTERED SALES OF EQUITY SECURITIES AND USE OF PROCEEDS

None.

ITEM 3. DEFAULTS UPON SENIOR SECURITIES

None.

ITEM 4. MINE SAFETY DISCLOSURES

None.

ITEM 5. OTHER INFORMATION

None.

ITEM 6. EXHIBITS

Exhibit No.	Description of Exhibit
2.1	Agreement and Plan of Merger and Reorganization dated September 27, 2007, by and among the Company, Biopath Acquisition Corp., a Utah corporation and wholly owned subsidiary of the registrant, and Bio-Path, Inc., a Utah corporation (incorporated by reference to Exhibit 2.1 to the Company's Current Report on Form 8-K filed on September 27, 2007).
3.1	Certificate of Incorporation (incorporated by reference to Exhibit 3.3 to the Company's Current Report on Form 8-K filed on January 6, 2015).
3.2	Certificate of Amendment to the Certificate of Incorporation of Bio-Path Holdings, Inc. (incorporated by reference to Exhibit 3.1 to the Company's Current Report on Form 8-K filed on February 9, 2018).
3.3	First Amended and Restated Bylaws (incorporated by reference to Exhibit 3.1 to the Company's Current Report on Form 8-K filed on June 7, 2017).
3.4	Certificate of Amendment to the Certificate of Incorporation of Bio-Path Holdings, Inc. (incorporated by reference to Exhibit 3.1 to the Company's Current Report on Form 8-K filed on January 16, 2019).
10.1	Second Amendment to Bio-Path Holdings, Inc. 2017 Stock Incentive Plan (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 10-Q filed on May 14, 2020).
10.2	At-the-Market Offering Agreement, by and between Bio-Path Holdings, Inc. and H.C. Wainwright & Co., LLC, dated July 13, 2020 (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed on July 14, 2020).
31*	Certification of Principal Executive Officer and Principal Financial Officer pursuant to Exchange Act Rules 13a-14 and 15d-14, as adopted pursuant to Section 302 Sarbanes Oxley Act of 2002.
32**	Certification of Principal Executive Officer and Principal Financial Officer pursuant to Section 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes Oxley Act of 2002.
101.INS*	XBRL Instance Document
101.SCH*	XBRL Taxonomy Extension Schema Document
101.CAL*	XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF*	XBRL Taxonomy Extension Definition Linkbase Document
101.LAB*	XBRL Taxonomy Extension Label Linkbase Document
101.PRE*	XBRL Taxonomy Extension Presentation Linkbase Document

* Filed herewith.
** Furnished herewith.

SIGNATURE

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

Dated: August 13, 2020	BIO-PATH HOLDINGS, INC.
	By: /s/ Peter H. Nielsen Peter H. Nielsen President Chief Executive Officer (Principal Executive Officer) Chief Financial Officer (Principal Financial Officer)

Exhibit 31

CERTIFICATION OF
PRINCIPAL EXECUTIVE OFFICER AND
PRINCIPAL FINANCIAL OFFICER

I, Peter H. Nielsen, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Bio-Path Holdings, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. I am responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under my supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to me by others within those entities, particularly during the period in which this report is being prepared;

b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under my supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

c) Evaluated the effectiveness of the registrant’s disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. I have disclosed, based on my most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant’s board of directors:

a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Dated: August 13, 2020

By: /s/ Peter H. Nielsen
Peter H. Nielsen
Chief Executive Officer
(Principal Executive Officer)
Chief Financial Officer
(Principal Financial Officer)

Exhibit 32

**CERTIFICATION PURSUANT TO 18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002**

In connection with the Quarterly Report on Form 10-Q of Bio-Path Holdings, Inc. (the “Company”) for the quarter ended June 30, 2020 as filed with the Securities and Exchange Commission (the “Report”), I, Peter H. Nielsen, Chief Executive Officer and Chief Financial Officer of the Company, certify, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, that:

(1) the Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Dated: August 13, 2020

By: /s/ Peter H. Nielsen
Peter H. Nielsen
Chief Executive Officer
Chief Financial Officer